Standards and Calibration Laboratory

Document Control

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DOCUMENT CONTROL

1.0 PURPOSE

This document describes the requirements for the preparation, identification, review, approval, distribution, revision, and control of quality-affecting documents. Quality-affecting documents are those documents that define procedures for the operation of the Standards and Calibration Laboratory.

2.0 CONTROLLED DOCUMENTS

The following documents are controlled using the methods described in this procedure.

- Planning Documents
- Documentation Memos
- Standard Operating Procedures
- ES&H Documents
- Calibration Procedures
- Dataforms
- Uncertainty Calculation Forms

3.0 DOCUMENT ORIGINALS

The signed original and all subsequent revisions of each controlled document are maintained as hard copies in a locked file controlled by the Quality Assurance Specialist.

4.0 ELECTRONIC DOCUMENT CONTROL SYSTEM

The current version of each controlled document is maintained on the group server as a read-only file that is accessible to all group members. Unless otherwise specified in this document, access to controlled documents can only be obtained through the electronic document control system. Hard copies, when required, must be printed at the time of use. The Programmer/Quality Assurance Officer is responsible for maintaining the documents on this system.

5.0 IDENTIFICATION OF DOCUMENTS

5.1 Header

Controlled documents are identified by means of a two-line header. The first line contains the letters SCL, indicating that the document was originated by the Standards and Calibration Laboratory, a two- to three-letter document series designator, a four-digit document number, and the effective date (date of final approval signature) of the document. The second line contains the words *Original Issue* (for the first version of a document) or the words *Replaces Version Dated* and the date of the version being replaced (for revisions to a document). The identification system for Dataforms is consistent with that for other controlled documents, but all Dataforms must have the same number as their corresponding Calibration Procedure (if any), and each Dataform number must have an alpha suffix. Requirements for identification of Dataforms are described in the section of this document titled

Dataforms. The following are sample headings that would apply to Planning Documents.

SCL-PD-0000, xx/xx/xx
Original Issue

Or

SCL-PD-0000, xx/xx/xx
Replaces Version Dated yy/yy/yy

5.2 Document Series Designator

The following designators are used to identify which series a document belongs to.

Designator	Document Series
PD	Planning Documents
DM	Documentation Memos
SOP	Standard Operating Procedures
ESH	Environment, Safety, and Health Documents
CP	Calibration Procedures
DF	Dataforms
UNC	Uncertainty Calculation Forms

5.3 Document Number

Documents in each document series are numbered sequentially beginning with the number 0001. A logbook is maintained for each document series in order to assure that a number is not assigned to more than one document.

6.0 DOCUMENT REVIEW PROCESS

With the exception of Documentation Memos and Dataforms, the original hard copy of each controlled document must be signed and dated by the preparer, a reviewer, and an approver. Because they are often required on a fast-turnaround basis, Documentation Memos and Dataforms are signed and dated only by the preparer and an approver. The personnel who are authorized to perform these functions for each type of controlled document are identified in the following sections.

7.0 CHANGE NOTIFICATION

When controlled documents are originated, changed, or retired, it is the responsibility of the approving authority to notify the appropriate members of the group. Notification may be verbal or in writing.

8.0 PLANNING DOCUMENTS

8.1 Description of Document Series

The Planning Document series of controlled documents are used to describe the Standards and Calibration Laboratory quality assurance program.

8.2 Format

Each Planning Document must have a cover page with the words "Standards and Calibration Laboratory" and the title of the procedure prominently centered on the page. The cover page must contain three signature lines, one for the preparer, one for the reviewer, and one for the Group Leader. It is suggested that topics within the body of the document be numbered and titled.

8.3 Preparation, Review, and Approval

The need for Planning Documents is determined by the Group Leader based on the requirements of the group. The Group Leader designates a member of the group to write the original planning document; this person signs and dates it when complete. The document is then reviewed and signed by a second member of the group designated by the Group Leader. It becomes official upon final review and signature by the Group Leader.

8.4 Distribution

Because it contains information and illustrations that are frequently referenced by group members in the normal course of their work, six official copies of SCL-PD-0002 *Calibration Process Manual* are maintained in hard copy form by the Quality Assurance Specialist. One copy resides in the physical section, another in the electrical section, and a third in the dimensional section. One additional copy resides with the Group Leader, the Programmer/Quality Assurance Officer, and the Quality Assurance Specialist. Hard copies of SCL-PD-0010 *Calibration Intervals* are distributed in the same manner, with the exception that the Quality Assurance Specialist retains the original rather than a copy.

8.5 Revision

Revisions to Planning Documents are prepared, reviewed, and approved in the same manner as originals.

8.6 Retirement

Planning Documents are considered active until they are either canceled or incorporated into another controlled document. In order to make a Planning Document inactive, the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

9.0 DOCUMENTATION MEMOS

9.1 Description of Document Series

Documentation Memos are used to institute new procedures or to make changes to existing procedures on a fast-turnaround basis when time does not permit the establishment or revision of a controlled document in another series. In most cases, Documentation Memos are eventually incorporated into another controlled document, but when there is no clear location for them in another document, they may be allowed to stand alone indefinitely.

9.2 Preparation, Review, and Approval

Documentation Memos may be prepared by any group member. They become official upon review and approval by the Group Leader.

9.3 Format

Documentation Memos should be formatted similar to official Laboratory memoranda. They must contain the effective date, the name and initials of the author, the name and initials of the Group Leader, and a title. The body of the memo may be in any format.

9.4 Distribution

After approval, hard copies of each Documentation Memo are distributed by the Administrative Assistant to all affected members of the group. Group members are not required to save these hard copies, but are required to read them and make a mental note that a new procedure has been implemented.

9.5 Revision

Revisions to Documentation Memos are prepared, reviewed, and approved in the same manner as originals.

9.6 Retirement

Documentation Memos are considered active until they are either canceled or incorporated into another controlled document. In order to make a Documentation Memo inactive, the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation.

10.0 STANDARD OPERATING PROCEDURES

10.1 Description of Document Series

Standard Operating Procedures are documents that describe the procedures and controls for conducting potentially hazardous activities or operations.

10.2 Format

Each Standard Operating Procedure must have a cover page with the words "Standards and Calibration Laboratory" and the title of the procedure prominently centered on the page. The cover page must contain three signature lines, one for the preparer, one for the reviewer, and one for the Group Leader. It is suggested that topics within the body of the document be numbered and titled.

10.3 Preparation, Review, and Approval

The need for a Standard Operating Procedure is determined by the Group Leader. Standard Operating Procedures are required when the hazard associated with an operation cannot be reduced to an acceptable level through other forms of mitigation, such as training or engineering controls. Once need has been established, the Group Leader designates a member of the group to write the Standard Operating Procedure; this person signs and dates it when complete. The document is then reviewed and signed by another person familiar with the hazards involved; often this person resides in an organization outside of the group. The Standard Operating Procedure becomes official upon final review and signature by the Group Leader.

10.4 Distribution

Except for the signed original, official versions of Standard Operating Procedures are not maintained in hard copy form.

10.5 Revision

Revisions to Standard Operating Procedures are prepared, reviewed, and approved in the same manner as originals.

10.6 Retirement

Standard Operating Procedures are considered active until they are either canceled or incorporated into another controlled document. In order to make a Standard Operating Procedure inactive, the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

11.0 ES&H DOCUMENTS

11.1 Description of Document Series

The ES&H series of documents describe the group's environment, safety, and health program.

11.2 Format

Each ES&H Document must have a cover page with the words "Standards and Calibration Laboratory" and the title of the procedure prominently centered on the page. The cover page must contain three signature lines, one for the preparer, one for the reviewer, and one for the Group Leader. It is suggested that topics within the body of the document be numbered and titled.

11.3 Preparation, Review, and Approval

The need for ES&H Documents is determined by the Group Leader based on the requirements of the group. The Group Leader designates a member of the group to write the original ES&H document; this person signs and dates it when complete. The document is then reviewed and signed by a second member of the group designated by the Group Leader. It becomes official upon final review and signature by the Group Leader.

11.4 Distribution

Except for the signed original, official versions of ES&H Documents are not maintained in hard copy form.

11.5 Revision

Revisions to ES&H Documents are prepared, reviewed, and approved in the same manner as originals.

11.6 Retirement

ES&H Documents are considered active until they are either canceled or incorporated into another controlled document. In order to make a ES&H Document inactive, the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

12.0 CALIBRATION PROCEDURES

12.1 Description of Document Series

Calibration Procedures are used to define the standard method used by the Standards and Calibration Laboratory for calibration of a particular type of equipment.

12.2 Format

Each Calibration Procedure must have a cover page with the words “Standards and Calibration Laboratory” and the title of the procedure prominently centered on the page. The cover page must contain three signature lines, one for the preparer, one for the reviewer, and one for the Group Leader. In order to assure uniformity, specific requirements have been developed for the format and content of Calibration Procedures. These requirements are described in Appendix 1 of this document.

12.3 Preparation, Review, and Approval

Calibration Procedures are developed as time and resources permit in order to increase the formality of operations within the Standards and Calibration Laboratory. The appropriate Team Leader or the Group Leader designates a member of the group to write the original Calibration Procedure; this person signs and dates it when complete. The document is then reviewed and signed by the Quality Assurance Specialist or the Programmer/Quality Assurance Officer. It becomes official upon final

review and signature by the appropriate Team Leader or the Group Leader.

12.4 Distribution

Except for the signed original, official versions of Calibration Procedures are not maintained in hard copy form.

12.5 Revision

Revisions to Calibration Procedures are prepared, reviewed, and approved in the same manner as originals.

12.6 Retirement

Calibration Procedures are considered active until they are either canceled or incorporated into another controlled document. In order to make a Calibration Procedure inactive, the appropriate Team Leader or the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

13.0 DATAFORMS

13.1 Description of Document Series

Dataforms are used to record measurements made during a calibration. They often contain other information, such as tolerance limits or equipment lists, that assist in the performance of the calibration.

13.2 Format

In order to assure uniformity, specific requirements have been developed for the format and content of Dataforms. These requirements are described in Appendix 2 of this document.

13.3 Identification of Dataforms

The identification system for Dataforms is consistent with that for other controlled documents, but all Dataforms must have the same number as their corresponding Calibration Procedure (if any). In addition, each Dataform number must have an alpha suffix. If no Calibration Procedure exists for the Dataform being written, or if the Calibration Procedure requires only one Dataform, the suffix "A" will be used (e.g., if the Calibration Procedure is numbered SCL-CP-400, its corresponding Dataform will be SCL-DF-400A). If the Calibration Procedure has multiple dataforms, the first dataform number will have the suffix "A," and subsequent dataforms will have suffixes B, C, D, etc.

13.4 Preparation, Review, and Approval

Dataforms are developed as time and resources permit in order to increase the formality of operations within the Standards and Calibration Laboratory. The appropriate Team Leader or the Group Leader designates a member of the group to write the original Dataform. In general, dataforms are originated by the person who is primarily responsible for a category of equipment because he or she can better determine the requirements for calibrating that equipment. The Dataform review process, described in Appendix 3, differs from that for other controlled documents in that only two signatures (the originator and the Quality Assurance Specialist or the Programmer/Quality Assurance Officer) are required for review and approval. This special review process allows changes to be made with a minimum of difficulty, as is often necessary when a dataform must be developed or modified in order to perform a time-critical calibration.

13.5 Distribution

Except for the signed original, official versions of Dataforms are not maintained in hard copy form.

13.6 Revision

Revisions to Dataforms are prepared, reviewed, and approved in the same manner as originals. Dataforms are usually revised by the original author unless primary responsibility for the category of equipment resides with someone else.

13.7 Retirement

Dataforms are considered active until they are either canceled or incorporated into another controlled document. In order to make a Dataform inactive, the appropriate Team Leader or the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

14.0 UNCERTAINTY CALCULATION FORMS

14.1 Description of Document Series

The Uncertainty Calculation Form series of controlled documents are used to document the method used to calculate the uncertainty assigned to a particular type of calibration.

14.2 Format

Each Uncertainty Calculation Form must have a cover page with the words “Standards and Calibration Laboratory” and the title of the uncertainty calculation prominently centered on the page. The cover page must contain three signature lines, one for the preparer, one for the reviewer, and one for the Group Leader.

14.3 Preparation, Review, and Approval

Uncertainty Calculation Forms are developed as time and resources permit in order to increase the formality of operations within the Standards and Calibration Laboratory. The appropriate Team Leader or the Group Leader designates a member of the group to write the original Uncertainty Calculation Form; this person signs and dates it when complete. The document is then reviewed and signed by a second member of the group designated by the appropriate Team Leader or the Group Leader. It becomes official upon final review and signature by the appropriate Team Leader or the Group Leader.

14.4 Distribution

Except for the signed original, official versions of Uncertainty Calculation Forms are not maintained in hard copy form.

14.5 Revision

Revisions to Uncertainty Calculations are prepared, reviewed, and approved in the same manner as originals.

14.6 Retirement

Uncertainty Calculation Forms are considered active until they are either canceled or incorporated into another controlled document. In order to make an Uncertainty Calculation Form inactive, the Group Leader writes on the face of the current version its retirement date and disposition (e.g., canceled or incorporated into another document), and initials the notation. The Programmer/Quality Assurance Officer then removes the document from the electronic document control system.

APPENDIX 1: REQUIREMENTS FOR THE FORMAT AND CONTENT OF CALIBRATION PROCEDURES

The following defines the format and content for writing calibration procedures. The primary reference used for establishing this outline and format is NCSL Recommended Practice RP-3, "Calibration Procedures: Content and Format for Measuring and Test Equipment, Measurement Standards, and Measurement/Test Systems."

1.0 INTRODUCTION

1.1 Describe the unit to be calibrated. State the environmental conditions at which the unit must be calibrated if applicable (reference *SCL-PD-0005 Environmental Control).*

1.2 Define the functional and performance specifications by tolerance/parameters that can be measured for the unit under calibration.

2.0 REQUIREMENTS

2.1 List the Measurement Standards (MS) and Measurement and Test Equipment (M&TE) used to test the unit under calibration. Include the manufacturer and model number.

2.2 Define the performance specifications required for the MS and M&TE.

3.0 MEASURING SYSTEM SETUP

3.1 List all preliminary actions, including functional checks, to be performed before starting the procedure described in Section 4.

Note: This section should include any safety precautions and the warm-up or stabilization period required to operate to specified tolerances.

4.0 TEST AND CALIBRATION PROCEDURE

4.1 List instructions and all steps to be performed in the measurement process. The clarity and degree of detail should be consistent with the technical complexity required to perform the measurement.

5.0 TEST DOCUMENTATION

5.1 List all records generated as a result of performing the procedure.

Note: If desired, the test documentation may be recorded on a stand-alone dataform that is referenced from the calibration procedure but not included in it.

6.0 REFERENCES

6.1 List any documents on which the procedure is based.

APPENDIX 2: REQUIREMENTS FOR THE FORMAT AND CONTENT OF DATAFORMS

All dataforms must have a header located at the top of the first page (subsequent pages need not have a header). It must say "Los Alamos National Laboratory" in a font similar to (but not necessarily the same as) the one below, and may be centered or not, as desired by the originator. The words "Standards and Calibration Laboratory" must also appear near the top of the first page; these words may be in any font and any location.

Los Alamos
NATIONAL LABORATORY

All dataforms must contain the following **required administrative data fields,** located below the header and above any technical data fields:

File Number (with blank space to be filled in by calibrator)
Category (Area and Subdivision) of item under test *
Item Name of item under test *
Manufacturer of item under test *
Model Number of item under test *
Calibration Date (with blank space to be filled in by calibrator)
Calibrated by (with blank space to be filled by calibrator)

The dataform may contain any number of **optional administrative data fields** desired by the originator. Examples of this type of field are: serial number, property number, other ID, contact, group, phone number, mail stop, calibration interval, expiration date, grade before and after adjustment, procedure reference, calibrated equipment used, and CBU equipment used.

The administrative data fields are followed by the technical data fields, where the results of the calibration are recorded. These data fields may be in any format desired.

The data form number, date of issue, and date of previous version (or the words "original issue") must appear near the top of each page of the dataform and may be made part of the header or the administrative fields, as desired. Each page of the dataform must be numbered. Note that some dataforms, especially in the electrical section, contain a "Specification" page that precedes the dataform. This page should not be numbered and must be formatted exactly as described in the Calibration Process Manual.

*The data for these fields may be specified on the dataform, or they may be blank fields to be filled in by the calibrator.

APPENDIX 3: DATAFORM REVIEW PROCESS

The review and approval of Dataforms is conducted according to the process shown below. The purpose is to allow Quality Assurance to retain a copy of both the draft Dataform, which has the approval signatures on it, and the final Dataform, which is suitable for inclusion in the calibration report package.

1. Originator creates or modifies draft Dataform in word processor, leaving date blank.

2. Originator prints and stamps[1] draft Dataform, and signs and dates stamp.

3. QA[2] reviews Dataform and returns to originator for correction or signs and dates stamp.

4. Signed and dated draft Dataform is returned to originator.

5. Originator dates Dataform in word processor using date signed by QA and prints final Dataform. At this point, dataform is approved and ready to use.

6. Draft Dataform with signatures, final Dataform, and final Dataform on diskette are returned to QA.

7. QA logs Dataform into approved Dataform database, files both draft Dataform and final Dataform, and copies diskette to group server.

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[1]The Dataform stamp contains the following four lines:

Originated by:_____
Date:_____
Reviewed by:_____
Date:_____

[2]QA refers to either the Quality Assurance Specialist or the Programmer/Quality Assurance Officer.